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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,063	01/28/2002	Norihito Shimono	2002-0055A	8747

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/048,063

Applicant(s)

SHIMONO ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other:

DETAILED ACTION

Papers Received

Preliminary Amendment received on 01/28/02 and Information Disclosure Statement received on 03/14/02.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al (USPN 5,731,006) in view of Sekigawa et al (USPN 5,217,720) or vice versa.

4. Claims 1- 5, 7, 8, and 10 – 15 are drawn to a solid preparation comprising chitosan powder, water-insoluble polymers such as ethyl cellulose and other cellulose ethers, and an enteric polymer such as hydroxypropyl methylcellulose acetate succinate and other cellulose ethers. The claims recite specific ratios of the chitosan to the water-insoluble polymer. The claims also recite that the preparation is in the form of a tablet, pellet pill or capsule. Claims 6

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and 9 recite a process for preparing the preparation comprising dispersing the chitosan into the water-insoluble polymer and coating this onto a medicament.

5. Akiyama teaches a composition which comprises chitosan, water-insoluble polymers and enteric polymers. The composition can be used as a coating for tablet, pellets and pills. Some of the enteric polymers named as being useful are hydroxypropyl methylcellulose phthalate and the like. The reference does not name the same water-insoluble polymers yet discloses their various commercially available methacrylic acid copolymers such as Eudragit E100, L-30-D-55, and RS for example. These commercially available polymers are recognized by applicant as being equivalent to the claims polymers with regard to their use in the best mode of the invention. The reference also suggests that the composition of the invention can be used to coat tablets, pellets and pills. The coating is also useful in the gastrointestinal tract (Abstract; col. 2, lin. 50 – 55; col. 4, lin. 1 – 5; col. 9, lin. 17 – 30; col. 11 – 12, lin. 60 – 9; claims). The reference however discloses their commercially available, art recognized equivalents; the reference does also does not explicitly teach the method of applicant. The reference merely suggests that the composition can be used, as a coating yet does not give a coating procedure.

6. However, Sekigawa et al discloses a coating procedure comprising dissolving chitosan in a mixture of cellulose ethers and coating it to a medicament core and further coating with an enteric polymer. The reference discloses a tablet for use in the gastrointestinal tract, double or triple coated with chitosan first, followed by enteric polymers such as hydroxypropyl methyl cellulose acetate succinate (Abstract; col. 1 – 2, lin. 55 – 35; col. 5, lin. 5 – 10, and 32 – 68, claims). The cellulose ethers named by Sekigawa are equivalent to those disclosed by Akiyama as both enteric polymers and water-insoluble polymers.

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The references also do not disclose the ratios of claims 4, 11 and 12, yet they teach the general combination of the components. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various coating pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claims 1, 8 and their subsequent dependent claims, these claims are considered product by process claims. The prior art provides a coated medicament where the coating comprises chitosan, water-insoluble polymers and enteric polymers. The limitation that the preparations are “produced by coating a medicament...” does not impart patentability over the prior art, since the claims are drawn to a product. The process by which a product is made is irrelevant when a product is claimed. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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With this in mind, due to the similarities between the coating polymers one of ordinary skill in the art would be motivated to follow the suggestions and teachings of the art. A skilled artisan would have followed the teaching of Akiyama that for coating a medicament, some enteric polymers also classify as water-insoluble polymers, and could have used this coating as the first layer in the pharmaceutical of Sekigawa. The skilled artisan would have been motivated to do so since the references shared similar polymer coatings such as hydroxypropyl methylcellulose phthalate and other cellulose ethers, and since both were for use in the gastrointestinal tract. Sekigawa provides a process for coating the medicament where the core is coated with a first layer of polymer/chitosan mixture followed by a layer of enteric polymers. The skilled artisan would have used the coating of Akiyama as the first layer, and followed it with the remaining cellulose ethers of Sekigawa. It would have been obvious to one of ordinary skill in the art to combine the teachings as such with an expected result of a coated medicament where the coating comprises chitosan, a water-insoluble polymer and an enteric polymer.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Suzuki et al (USPN 5,283,064), Iida et al (USPN 5,188,840), Lerner et al (USPN 5,840,332) and Illum (USPN 5,744,166) all teach solid drug composition with coatings consisting of chitosan, and enteric polymers such as the cellulose ethers claimed by applicant.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005.

The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

M. Young
November 29, 2002

 THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600